

SECTION 7: 510(K) SUMMARY

DEC 12 2012

1 INTRODUCTION:

- 1.1 This document contains the 510(k) summary for the VSP® System. The content of this summary is based on the requirements of 21 CFR 807.92.

2 APPLICANT NAME AND ADDRESS:

Name: Medical Modeling Inc.
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Official Contact: Andrew Christensen
President

**Summary
Preparation Date:** December 12, 2012

3 DEVICE NAME AND CLASSIFICATION

Trade Name: VSP® System

Common Name: System for the creation of patient specific anatomical models, templates, guides, and surgical plans

**Classification
Name:** Bone Cutting Instrument and Accessories

Classification: Class II, 21 CFR 872.4120

Product Code: DZJ, LLZ

4 PREDICATE DEVICES:

- 4.1 The VSP® System is claimed to be substantially equivalent to the following legally marketed predicate devices:

- 4.1.1 CT Modeller (K970617), manufactured by Materialise®
- 4.1.2 SurgiCase® Guides (K103136), manufactured by Materialise®
- 4.1.3 SimPlant® 3Matic® (K060950), manufactured by Materialise®
- 4.1.4 MIMICS® (K073468), manufactured by Materialise®

5 PERFORMANCE STANDARDS:

- 5.1 There are no performance standards for this device type

6 DESCRIPTION OF THE DEVICE:

- 6.1 The Medical Modeling VSP® System is a collection of software and associated additive manufacturing (rapid prototyping) equipment intended to provide a variety of outputs to support reconstructive surgery. The system uses electronic medical images of the patients' anatomy with input from the physician, to manipulate original patient images for planning and executing surgery. The system produces a variety of patient specific outputs including; anatomical models (physical and digital), surgical templates / guides, splints, and patient specific case reports.
- 6.2 Following the Medical Modeling Quality System and specific Work Instructions, trained employees utilize a combination of Commercial Off-The-Shelf (COTS) and custom software to manipulate 3-D medical scan images which can include Computed Tomography (CT), Cone Beam CT (CBCT), and/or 3-D scan images from patient physical models (stone models of the patient's teeth) to create patient-specific physical and digital outputs. The process requires clinical input and review from the physician during planning and prior to delivery of the final outputs. While the process and data-flow vary somewhat based on the particular requirements of a given patient and physician, the following description outlines the functions of key sub-components of the system, and how they interact to produce the defined system outputs. It should be noted that the system is operated only by trained Medical Modeling employees, and the physician does not directly input information. The physician provides input for model manipulation and interactive feedback through viewing of digital models of system outputs that are modified by the engineer during the planning session.
- 6.3 The VSP® System is made up of 13 individual pieces of software and 9 pieces of manufacturing equipment integrated to provide a range of anatomical models (physical and digital), surgical guides, and patient specific planning reports for reconstructive surgery in the maxillofacial region. Surgical guides for graft bone harvesting which can include the fibula and hip are also produced by the system.
- 6.4 The VSP® System requires an input 3-D image file from medical imaging systems (i.e. – CT). This input is then used, with support from the prescribing physician to provide the following potential outputs to support reconstructive surgery. Each system output is designed with physician input, and reviewed by the physician prior to finalization. All outputs are used only with direct physician involvement reducing the criticality of the outputs.
- 6.5 System Outputs
 - 6.5.1 Anatomical Models
 - 6.5.2 Surgical Positioning Templates / Guides
 - 6.5.3 Osteotomy Templates / Guides
 - 6.5.4 Plate Bending Templates/Guides
 - 6.5.5 Patient Specific Case Reports
- 6.6 The VSP® System also contains a set of Stainless Steel Cutting and Drill Inserts (VSP® System Accessories) which are intended to be used by the physician to guide cutting and drilling activities during the surgical procedure. The inserts fit into a

standard slot/hole in the cutting/drill guides, and can be used across all the VSP® System guides and templates.

7 INDICATIONS FOR USE

- 7.1 The Medical Modeling VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

8 COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS

- 8.1 The VSP® System has a similar intended use and similar technological characteristics as the identified predicate devices. The potential impact on substantial equivalence of each technologic difference was addressed by provided safety and performance testing as described in section 9 below.
- 8.1.1 The system employs similar fundamental technologies as the identified predicates including:
- 8.1.1.1 Software for image transfer, manipulation, and surgical planning;
 - 8.1.1.2 Hardware for rapid manufacturing of patient specific anatomical models, guides and templates.
- 8.1.2 The principles of operation and technological characteristics are all either identical, or substantially equivalent between the VSP® System and the four identified predicates.
- 8.1.3 The system has similar technical characteristics including:
- 8.1.3.1 System Inputs: Images from medical scanners (i.e. CT);
 - 8.1.3.2 System Outputs: Physical and digital outputs such as patient specific anatomical models, cutting and drill guides, templates and splints;
 - 8.1.3.3 Materials: Biocompatible polymers and surgical instrument grade stainless steel;
 - 8.1.3.4 Sterility Assurance Level: 1×10^{-6} .
- 8.1.4 The intended use of the VSP® System and its predicates are substantially equivalent in the following respects:
- 8.1.4.1 All the of the devices are intended to provide tools and accessories (software for image manipulation, anatomical models, guides and templates) for use in reconstructive surgery;
 - 8.1.4.2 The VSP® System and the identified predicates are all intended to be used by trained personnel, in a non-medical manufacturing or office environment, with active support from the surgeon;

- 8.1.4.3 The VSP® System and the identified predicates are all intended for use on surgical candidates undergoing complex reconstructive or anatomical modification surgery.
- 8.1.5 The VSP® System Accessories are manufactured to ASTM F899-11 and are sterilized by the healthcare facility with the same cycle as the other system outputs. The addition of the VSP® System Accessories does not change the intended use of the system; therefore, the determination of substantial equivalence between the VSP® System and its predicates remains unaffected.

9 SUMMARY OF PERFORMANCE TESTING

- 9.1 Section 9.3 below outlines the categories of Verification and Validation testing performed on the VSP® System as a part of Medical Modeling's Design Control Program. The testing outlined below was intended to show that the output of the design and development process including labeling and packaging demonstrated compliance with the device specifications and intended uses.
- 9.2 Because the VSP® System is actually the combination of a manufacturing process and the patient specific outputs of the manufacturing process (models, guides and templates), the performance testing for the device included methods typical of process validation (IQ, OQ, PQ) with the intention to show that the manufacturing process could correctly translate 3 dimensional electronic models of patient anatomies, templates and guides into matching physical models within the allowed tolerance ranges from the process specifications.
- 9.3 Device performance verification and validation testing conducted on the VSP® System included:
 - 9.3.1 Installation Qualification (IQ)
 - 9.3.1.1 Equipment Installation
 - 9.3.1.2 Process Inputs
 - 9.3.1.3 Procedures and Work Instructions
 - 9.3.1.4 Training
 - 9.3.2 Operational Qualification (OQ) – performance over the range of allowable process parameters
 - 9.3.2.1 Visual / Dimensional Testing
 - 9.3.2.2 Mechanical Testing
 - 9.3.2.3 Cytotoxicity Testing
 - 9.3.3 Performance Qualification (PQ) – performance at nominal parameters to demonstrate consistency and repeatability
 - 9.3.3.1 Visual / Dimensional Testing
 - 9.3.3.2 Mechanical Testing
 - 9.3.4 Software Validation

- 9.3.4.1 Verification of each independent software subsystem against defined requirements
- 9.3.4.2 Verification of interfaces between software subsystems against defined interface requirements
- 9.3.4.3 Validation of fully integrated system including all subsystems against overall system requirements
- 9.3.5 Simulated Use (Planning Session)
- 9.3.6 Labeling Validation
- 9.3.7 Cleaning Validation
- 9.3.8 Sterilization Validation
- 9.3.9 Biocompatibility
- 9.3.10 Packaging Validation
- 9.4 All Design, Process, and Other Verification and Validation Testing, which was required as a result of risk analysis and design impact assessments, showed conformity with pre-established specifications and acceptance criteria. The acceptance criteria were established in order to demonstrate device performance and substantial equivalence of the system to its defined predicate devices.

10 SUBSTANTIAL EQUIVALENCE

- 10.1 Based on a comparison of the intended use and technological characteristics, the VSP® System is substantially equivalent to the identified predicate devices. Minor differences in technological characteristics were demonstrated by performance data to have no effect on substantial equivalence and validation data supports that the system performs in accordance with its intended use and is substantially equivalent to the following predicate devices:
 - 10.1.1 CT Modeller (K970617), manufactured by Materialise®
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2012

Medical Modeling, Incorporated
C/O Mr. Jonathan S. Kahan
Partner
Hogan Lovells US, Limited Liability Partnership
555 Thirteenth Street, North West
WASHINGTON DC 20004

Re: K120956
Trade/Device Name: VSP® System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZJ, LLZ
Dated: December 3, 2012
Received: December 5, 2012

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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Radiological Health

Enclosure

K120956

Indications for Use

510(k) Number (if known): K120956

Device Name: VSP® System

Indications for Use:

The Medical Modeling VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices